

REMARKS

Applicant respectfully requests entry of the amendment and reconsideration of the claims. Claims 1-24 are pending. Claim 1 has been amended. The amendment is supported by the specification, for example, at page 4, lines 22-24, and does not introduce new matter.

Rejections under 35 U.S.C. § 112

Claims 1, 2, and 22-24 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Claims 2 and 22-24 depend from claim 1. The Office Action alleges claim 1 is incomplete insofar as it does not specify the frame of reference used to measure the nicotine release rate. Without acquiescing to the rejection and solely for the purpose of advancing prosecution, claim 1 has been amended to further recite that the nicotine release rate is determined according to U.S. Pharmacopeia (USP) Official Monograph, Volume 26 for nicotine polacrilex. The amendment is supported by the specification, for example, at page 4, lines 22-24.

Applicants submit the claims as amended comply with the requirements of § 112, second paragraph. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 1-22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Walling (U.S. 6,586,449) in view of Ferno (U.S. 3,845,217). Applicant respectfully traverses the rejection.

The Office Action alleges it is not clear if the data in the specification, in particular Table A, supports a conclusion of unexpected results. A declaration by the inventor Carsten Andersen under 35 U.S.C. § 1.132 (hereinafter the Declaration) is filed herewith. In the Declaration, Mr. Andersen provides the formulation for A and B in Table A and describes how the components were mixed together, including the amount and order in which the components were added during mixing, to form the final product. See paragraphs 10-12 in the Declaration. Mr. Andersen indicates that in 2010 a number of commercial full scale batches were produced using

the same materials as in A and B. The September 2010 testing data in Table A in the specification corresponds to the nicotine release data obtained for the commercial full scale batches. See the Declaration at paragraphs 13 and 15. The final products in Table A in the specification were tested for nicotine release rate according to USP Official Monograph, Volume 26, pages 1309-1310 for nicotine polacrilex, which is identical to the test method defined in USP Official Monograph, Volume 25, pages 1225-1226 used in the Walling reference. See Declaration at paragraph 14.

As discussed by Mr. Andersen, the average release rates were 81.7% for A, 80.2% for B, and 78.6% for the commercial full scale batches. These test results indicate an improvement in nicotine release relative to the data in Walling. The experiments described in the Declaration used glycerol as the polyol. Walling reported a release of only 71% in example 1, which uses glycerol as the polyol. See Declaration at paragraph 15.

In the Declaration, Mr. Andersen indicates the fact that a nicotine release rate of 80% or greater could be obtained was unexpected and surprising. In order to obtain a release rate greater than 70%, Walling discloses that it is necessary to combine the polyol with the cation exchange resin before admixture with the nicotine. According to Mr. Andersen, he did not expect that a nicotine release greater than the nicotine release rates in Walling (71-77%; see table 1 of Walling), much less nicotine release of 80% or greater, could be achieved by mixing the nicotine with the polyol prior to the cation exchange resin. See Declaration at paragraph 16.

In view of the Declaration and the data provided in the specification, Applicant submits a nicotine delivery product which has the same nicotine loading capacity as the compositions disclosed in Walling, but a nicotine release rate of at least 80% was an unexpected and surprising result. Walling does not provide any evidence that the methods disclosed therein are suitable for producing a composition having nicotine release greater than 77% and specifically teaches away from mixing the nicotine with the polyol prior to the cation exchange resin.

The Office Action acknowledges that Walling does not disclose the specific order of method steps recited in the claims or a chewing gum. The Office Action, however, alleges it would have been obvious to change the order of the process steps in Walling to arrive at the present claims as Ferno discloses that the release rate of nicotine can be varied by varying the

amount of nicotine bound to the cation exchange resin and that mixing the nicotine with the exchange resin in the first step would allow more nicotine to be bound to the resin before the addition of the polyol. Applicant does not agree.

First, the claims are supported by unexpected results for the reasons discussed above. Therefore, the selection of any order of performing process steps is not *prima facie* obviousness.

Second, it is well established that "a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." MPEP § 2141.02 citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983) *cert. denied*, 469 U.S. 851 (1984). It is improper to combine references where the references teach away from their combination. MPEP § 2145(X)(D)(2) citing *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983). Walling discloses that the nicotine release characteristics of a chewable smoking substitute, such as those disclosed in Ferno, are not sufficient as such gums are only marginally effective because nicotine release is small and in reduced amounts. See Walling at col. 1, lines 41-50. In order to obtain a release rate of 70% within 10 minutes, Walling discloses that it is necessary to combine the polyol with the cation exchange resin before admixture with nicotine. See col. 2, lines 56-58. Walling therefore specifically teaches away from mixing the nicotine with the polyol prior to the cation exchange resin.

Third, the nicotine delivery products disclosed by Applicant have the same nicotine loading capacity as the compositions disclosed in Walling. Contrary to the assertions in the Office Action, there is no teaching or suggestion in Ferno or Walling that adding more nicotine to the resin would enhance the rate of nicotine release from the resin. The enhanced nicotine release is a function of the polyol. The amount of nicotine in the Walling product is already at least 50% greater than the amount of nicotine in the product disclosed in Ferno (0.1 to 10% nicotine by weight, preferably 0.5 to 2 %; col. 8, lines 56-60), so there is no motivation as alleged in the Office Action to mix the nicotine with the exchange resin (as taught by Ferno) prior to addition of the polyol.

Finally, neither Walling nor Ferno discloses or suggests any advantage to mixing the nicotine with the cation exchange resin prior to addition of the polyol. In fact, Walling (which was published some 30 years after Ferno) specifically teaches away from such a method for the

reasons discussed above. Moreover, as discussed by Mr. Andersen in the Declaration, nothing in Ferno would suggest to one of skill in the art the order of addition of the various components of a nicotine-resin product is important, let alone that his might have an influence on the nicotine release rate of the product. See Declaration at paragraph 17. Therefore, one of skill in the art would not have been motivated to alter the addition order of ingredients as alleged in the Office Action.

In view of the foregoing, Applicant submits the cited combination of references fails to renders the claims obvious as the claims are supported by unexpected results. The test results provided by Applicant show that an unexpected effect (i.e. increase in nicotine release) is obtained by the order of steps recited in the claims. Withdrawal of the rejection is respectfully requested.

Double Patenting

Claims 1-22 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 3, 6, 10-15, and 19-22 of Application No. 10/921,199. Although the rejection cites Application No. 10/921,199, Applicant believes the Examiner intended to recite Application No. 11/921,199.

Applicant acknowledges the rejection and request that the rejection be held in abeyance until allowable subject matter is indicated.

If a provisional non-statutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications and the later-filed application is rejectable on other grounds, the Examiner should withdraw the provisional ODP rejection and permit the earlier filed application to issue as a patent without a terminal disclaimer. MPEP § 804(I)(B)(1). Applicant notes that the present application was filed on March 16, 2007, while copending Application No. 11/921,199 was filed on November 21, 2008. The present application is therefore the earlier filed of the two applications.

Conclusion

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

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Date: _____

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